

15090801

APR - 8 2009

**510(k) Summary
for
Electronic House Call™ System**

1. SPONSOR

Express MD Solutions, LLC
2001 Bomar Drive Suite 3
Palm Beach Gardens, FL 33408
Contact Person: Chris Doherty
Telephone: (617) 595-2700

2. DEVICE NAME

Proprietary Name: Electronic House Call™ System
Common/Usual Name: Telehealth System
Classification Name: Physiological Signal Transmitters and Receivers

3. PREDICATE DEVICES

- Health Buddy with Glucose Connectivity (K993128)
- Health Buddy with BuddyLink (K040086)
- Health Buddy with Device Connectivity(K042273)
- Health Buddy Appliance (K050567)
- Health Buddy Appliance, Health Hero Network (K060843)
- Neptec Care Companion Nurse and Patient Station K022274 and K023286
- RTX DLM112 Daylink Monitor (K062304)
- ZOLL M-Series NIBP Option (K032363)
- ZOLL E-Series NIBP Option (K042007)
- March Healthcare HMK (K060194)

4. DEVICE DESCRIPTION

The Express MD Electronic House Call™ System is comprised of a home unit, legally marketed diagnostic peripherals, and a server. The home unit is a communications device that collects data from the diagnostic peripherals and the

patient in the home and transmits the data to the server over the home's existing telephone line or other identified method (existing high-speed connection in patients' home). The diagnostic peripherals comprise a wide range of legally marketed medical electronic devices capable of measuring patient parameters such as blood pressure, pulse rate, weight, etc. The server application responds to calls from the home units, collects the data, and then compares the data to preset thresholds. The healthcare practitioners and privileged users access the server through a secure website.

If a patient is found to be outside of a pre-set parameter, the healthcare practitioner will respond according to their set policies. In addition, an email will be sent to the clinician. This email indicates that the nurse/clinician should review the website. This is not a real time alert or an alarm but an email that does not identify a patient, parameter or clinical state.

5. INTENDED USE

The Electronic House Call™ System (Electronic House Call™ Device + Electronic House Call™ Application + Electronic House Call™ website) is a remote, retrospective monitoring tool to supplement a patients' care. The Electronic House Call™ Device together with the Electronic House Call™ Application is intended to be a simple "store and forward" communications platform that allows clinicians and authorized users to access a patients' information for review through the Electronic House Call™ website. The Electronic House Call™ Device is a tool to monitor patients remotely and motivate them through education and reminders. The Electronic House Call™ System allows patients to measure vital signs without assistance from their healthcare provider. The Electronic House Call™ System is not intended to replace existing treatments or consultations, nor is it to be used as a substitute for a qualified healthcare professional's judgment or treatment plan. The Electronic House Call™ System is not intended to act as an emergency response system.

6. TECHNOLOGICAL CHARACTERISTICS AND SUBSTANTIAL EQUIVALENCE

The proposed Electronic House Call™ System and the predicate devices all consist of a home unit, peripheral devices, and a secure website. Both the proposed and predicate devices connect to a telephone line at the subject's home or assisted living facility. The peripheral devices that are compatible with the Electronic House Call™, the Neptec System, the RTX device and Health Buddy System include non-

invasive blood pressure cuffs, patient weight scales, and blood glucose meters. The proposed Electronic House Call™ System and the predicate Health Buddy devices are simple, user friendly devices that connect to a standard home telephone line. In addition to the standard phone line, the proposed Electronic House Call™ can connect to a Cingular 8525 cell phone or existing high-speed Ethernet line. These transmission protocols have been validated and do not affect safety or effectiveness of the device. The proposed and predicate device screens display information, take vital signs, and ask questions about symptoms and behaviors. Both the Electronic House Call™ System and the Health Buddy predicate devices provide education and reinforcement to the patient while delivering evaluation by a medical professional. Both the proposed Electronic House Call™ System and the RTX DLM112 Daylink Monitor include the option of communication using ECG systems. This option provides the user the ability to transmit ECG data from legally marketed ECG devices using standard digital communication technologies to the healthcare provider. This feature of the proposed and predicate devices does not raise any safety or effectiveness issues since verification and validation testing have been performed to support the function and compatibility of the ECG with the Electronic House Call™ System.

Like the proposed Electronic House Call™ System, the Health Buddy System includes software to record patient information and devices designed to receive information from the peripheral devices and then transfer the information to a secure website.

Additionally, a comparison of the intended use and technical characteristics of the proposed device with the Suntech Advantage Model 2 Blood Pressure kit and the Nonin iPod and their predicate devices demonstrates that the Electronic House Call™ System is substantially equivalent to both the ZOLL M-Series NIBP Option and the ZOLL E Series devices which utilize the Suntech Advantage Model 2 Blood Pressure kit and the March Healthcare HMK device which utilizes the Nonin iPod.

7. PERFORMANCE TESTING

Verification, validation and electrical safety/electromagnetic compatibility testing was performed to determine that the Electronic House Call™ System functions as intended and is safe and effective for its' intended use.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR - 8 2009

Express MD Solutions LLC
c/o Intertek Testing Services NA, Inc.
2307 E. Aurora Rd. Unit B7
Twinsburg, OH 44087
Attn: Daniel Lehtonen

Re: K090801
Trade/Device Name: Electronic House Call System
Regulation Number: 21 CFR 870.2910
Regulatory Class: Class II
Product Code: DRG
Dated: March 23, 2009
Received: March 24, 2009

Dear Mr. Lehtonen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

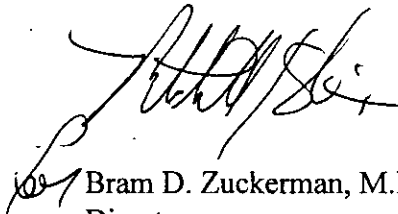
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please contact the CDRH/Office of Surveillance and Biometrics/Division of Postmarket Surveillance at 240-276-3464. For more information regarding the reporting of adverse events, please go to <http://www.fda.gov/cdrh/mdr/>.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Bram D. Zuckerman", is written over a horizontal line.

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known):

Device Name: Electronic House Call System

Indications for Use:

The Electronic House Call System (Electronic House Call Device + Electronic House Call Application + Electronic House Call Website) is a remote, retrospective monitoring tool for supplement in a patients' care. The Electronic House Call Device together with the Electronic House Call Application is intended to be a simple "store and forward" communications platform that allows clinicians and privileged users to access a patients' information for review through the Electronic House Call Website. The Electronic House Call Device is a tool to monitor patients' remotely and motivate them through education and reminders. The Electronic House Call System allows patients to measure vital signs without assistance from their healthcare provider. The Electronic House Call System is not intended to replace existing treatments or consultations, nor is it to be used as a substitute for a qualified healthcare professional's judgment/treatment plan. The Electronic House Call System is also not intended to act as an emergency response system.

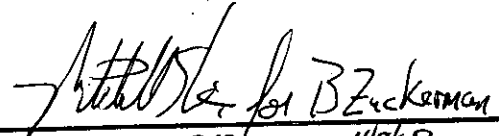
Prescription Use x
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)


(Division Sign-Off) 4/8/09
Division of Cardiovascular Devices
510(k) Number K090801